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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,683	09/26/2003	Chi-Hung Lin	9751.106USU1	9244
23552	7590	04/21/2005	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,683

Applicant(s)

LIN ET AL

Examiner

Raymond J. Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date March 22, 2005.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

CLAIMS 19-27 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment and Information Disclosure Statement filed March 22, 2005 have been received and entered into the application. Accordingly, claims 1, 2, 8-11, 17, 18, 28 and 29 have been canceled. Also, as reflected by the attached, completed copy of "FORM 1449*", the Examiner has considered the cited references.

In view of the above amendments, the rejections of (i) claims 1, 3, 8, 10, 11, 17 and 18 under 35 U.S.C. §102(e) as being anticipated by Saxena et al. (U.S. Patent Application Publication No. 2003/0092674) and (ii) claims 1, 3, 8, 10, 11, 17 and 18 under 35 U.S.C. §103(a) as being unpatentable over Saxena et al. in view of Bang et al. (U.S. Patent No., 5,248,696), as set forth in the previous Office action dated November 23, 2004 at pages 3-6, are moot and therefore withdrawn.

The error in the listing/consideration of the pending claims set forth in the previous Office action dated November 23, 2004 is acknowledged. In particular, as stated by Applicants at page 4 of the above referenced Amendment, "Claims 1, 3, 8-11 and 17-29, not claims 1, 3, 8, 11 and 17-26, should have been pending after entry of the Amendment dated October 22." The issue concerning the pendency/consideration of claim 9, 28 and 29 is moot because these claims have been canceled. Claim 27 is considered herein.

The indicated allowability of claims 19-26 is withdrawn in light of the newly presented issues below.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

“The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.” (MPEP 2173).

The term "derivative" in the expression "abietic acid or derivative thereof" (claims 19, 21, 25 and 27) is a relative term which renders the claim indefinite. In particular, "derivative" does not particularly point out the degree or type of derivation that a given compound may have in relation to abietic acid and still be considered a "derivative" as intended by Applicants. Therefore, the metes and bounds of the subject matter for which Applicants seek patent protection has not been adequately set forth.

In the present specification at the paragraph bridging pages 5-6, Applicants have set forth:

“The term ‘derivatives’ of abietic acid used herein refers to a group of compounds derived from abietic acid, which have a function substantially equivalent to that of abietic acid as described herein. For instance, the derivatives of abietic acid of the invention may be produced by incorporating a modification, such as dehydrogenation or substitution with one or more substituents, into abietic acid. According to the invention, a dehydroabietic acid and a substituted abietic acid are within the scope of the derivatives of abietic acid of the invention.”.

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Such disclosure, however, does not render the claims definite. Words and phrases in the claims must be given their "plain meaning" as understood by one having ordinary skill in the art unless defined by Applicant in the specification with "reasonable clarity, deliberateness and precision". (MPEP 2111.01). Here, Applicants' definition of "derivatives" is not reasonably clear, deliberate or precise because the definition employs not only the term itself which is being defined, i.e., "a group of compounds *derived* from abietic acid", but also is exemplary in nature and thus not precise, i.e., "For instance..." and "such as dehydrogenation...". Further, it is indicated that "substituted abietic acid" is included in the definition. However, neither the type nor degree of substitution is indicated.

Applicants have failed to provide an acceptable definition for the term "derivative" in the present specification and, lacking a clear meaning of this term, the skilled artisan would not be reasonably apprised of the type and degree of derivation intended. Whether or not a particular compound is included in or excluded by the claims would thus be open to subjective interpretation and such is inconsistent with the tenor and express requirements of 35 U.S.C. §112, second paragraph.

Accordingly, the claims are deemed properly rejected.

Suggestion for Overcoming this Rejection

Replacing the expression "derivative thereof" with ---dehydroabietic acid--- would overcome this ground of rejection.

Claim Rejection - 35 USC § 102

Claims 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Saxena et al. (U.S. Patent Application Publication No. 2003/0092674), already of record.

Saxena et al. teach the administration, which may be oral (page 9, section [0080], line 8), of a composition which comprises one or more abietic acid derivatives (page 3, sections [0019], [0020], [0022] and [0023]; page 4, sections [0026] and [0027]; and pages 10+ at claim 1) and a pharmaceutically acceptable carrier for the cancers including breast, cervix, i.e., cervical and liver, i.e., hepatic which would necessarily include hepatocellular (see page 17, claim 7 at lines 15, 18, 20 and 21 thereof).

While not expressly disclosed, the requirement of claim 25, i.e., “increasing the permeability of cervical carcinoma cells, hepatocellular carcinoma cells, or breast cancer cells”, and claim 27, i.e., “the cells swell and become round in morphology”, are deemed inherently disclosed in the reference because the same compounds would necessarily be administered to the same host suffering from the same cancer types as in the present claims.

Also, the requirement of claim 26 is not disclosed, i.e., “human”. However, the reference discloses “individual” (page 9, section [0076]), “subject” (page 9, section [0078]) and “mammal” (page 10, claim 1 at line 3 thereof) and such is deemed to represent a genus of sufficient size and nature that a human host would be placed within the possession of the public by the disclosure of Saxena et al.

To anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber*, 128 F.3d 1473, 1477, 44

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U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

Suggestion for Overcoming this Rejection

In order to overcome the present rejection, Applicants should amend at least claim 25 to include an express limitation, disclosed in the present specification, that is not necessarily present in the method of Saxena et al. For example, because Saxena et al. do not teach that the abietic acid compounds may be administered in combination with an anticancer drug, amending claim 25 to include contacting the cells with an anticancer drug would overcome the present rejection.


None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

April 17, 2005